

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte TODD MICHEL GROTE,  
BRIAN KEITH HUCKABEE,  
THOMAS MULHERN,  
DENIS MARTIN SOBIERAY,  
and  
ROBERT DANIEL TITUS

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Appeal No. 2003-1991  
Application No. 09/412,258

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and LIEBERMAN, Administrative Patent Judges.

LIEBERMAN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner refusing to allow claims 3 and 30, which are all the claims pending in this application.

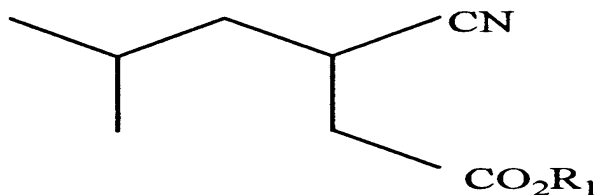
### THE INVENTION

According to the appellants, the invention is directed to a  $C_1$  to  $C_6$  alkyl ester of 3-cyano-5-methyl hexanoic acid. The invention is characterized by the formula in the following illustrative claim.

### THE CLAIM

Claim 3 is  
appellants'  
reproduced

3. The  
formula



illustrative of  
invention and is  
below:  
compound having the

wherein  $R_1$  is  $C_1$ - $C_6$  alkyl.

### THE REFERENCE OF RECORD

As evidence of obviousness, the examiner relies upon the following reference:

Benneville et al. (Benneville)

3,110,723

Nov. 12, 1963

### THE REJECTION

Claims 3 and 30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Benneville.

### OPINION

We have carefully considered all of the arguments advanced by the appellants and the examiner, and agree with the examiner for the reasons stated in the Answer and those set forth herein that the rejection of claims 3 and 30 under 35 U.S.C. § 103(a) is well founded. Accordingly, we affirm the rejection.

As an initial matter, it is the appellants' position that, "[c]laims 3 and 30 be grouped separately." See Brief, page 3. Accordingly, separate consideration will be given to each of the two claims to the extent required in our decision. See 37 CFR1.192(c)(7)(2002).

#### The Rejection under Section 103(a)

There is no dispute that the reference to Benneville is sufficient to establish a prima facie case of obviousness with respect to the claimed subject matter. The appellants readily concede that, "the subject matter of pending claim 3 and 30 is *prima facie* obvious over the disclosure of Benneville." See Brief, page 5.

Accordingly, the burden of proof of showing patentability shifts to the appellants to

present evidence rebutting the prima facie case of obviousness established by the examiner.

In doing so, "it falls upon the applicant to at least establish: (1) that there actually is a difference between the results obtained through the claimed invention and those of the prior art, *In re Klosak*, 455 F.2d 1077, 59 CCPA 862 (1972); and (2)

that the difference actually obtained would not have been expected by one skilled in the art at the time of the invention, *Id.*; *In re D'Ancicco*, 439 F.2d 1244, 58 CCPA 1057 (1971).” See *In re Freeman*, 474 F.2d 1318, 1324, 177 USPQ 139, 142 (CCPA 1973).

On the record before us, the claimed subject matter is directed to an intermediate compound, i.e., a C<sub>1</sub> to C<sub>6</sub> alkyl ester of 3-cyano-5-methyl hexanoic acid. The intermediate is thereafter hydrogenated to form the corresponding C<sub>1</sub> to C<sub>6</sub> alkyl ester of 3-aminomethyl-5-methyl hexanoic acid, also known as isobutyl-GABA. See specification, page 1, lines 16-18. The invention also provides for the resolution of racemic isobutyl-GABA to obtain the S-stereo isomer. See specification, page 3, lines 12-16.

The single reference before us to Benneville generically discloses the compounds of claims 3 and 30 and as admitted by the appellants is sufficient to establish a prima facie case of obviousness with respect to the claimed subject matter. The appellants in attempting to rebut the prima facie case of obviousness established by the examiner have introduced a declaration by Charles P. Taylor undisputedly presenting data that shows that racemic isobutyl-GABA and the S(+)-isobutyl isomer called pregabalin possess superior properties than corresponding homologous and analogous compounds. See Answer, pages 8 and 9.

It is the examiner's position that, "[t]he activity relied upon here, however, relates to known compounds known to possess the activity. By any definition a known property of a known compound cannot be characterized as unexpected." See Answer, pages 9-10.

On the record before us, we generally concur with the position by the examiner.

The appellants have presented a declaration directed not to the claimed intermediate but to the final product possessing pharmacological properties relying heavily upon In re Magerlein, 602 F.2d 366, 372-73, 202 USPQ 473, 479 (CCPA 1979) for its teaching that, "the capacity of an intermediate to contribute to an end product that feature which causes the end product to possess an activity or property that is unexpectedly superior to that of a prior art end product is a 'property' that inures to the benefit of the intermediate and that can be considered as part of the 'subject matter as a whole' in determining the nonobviousness of the intermediate."

Although, the submission of data directed to the end product in the case before us, would generally appear to be appropriate, in our view the facts before us are distinguishable from those of In re Magerlein cited above. On the record before us, the appellants admit that racemic isobutyl GABA was prepared in 1989. See specification, page 3, lines 1-3. They further admit that it was known in 1994 that the stereo selective isomer (S)-isobutyl GABA has anticonvulsant activity. See specification, page 2, lines 13-20.

Furthermore, the appellants have attached to the declaration of Charles P. Taylor a

publication by Taylor et al., Exhibit D, entitled "3-Alkyl GABA and 3-alkylglutamic acid analogues: two new classes of anticonvulsant agents," Epilepsy Res., pp. 103-110, Vol. 11 (Elsevier, 1992). We find that Table II on page 106 contains data directed to the prevention of seizures in mice by low intensity electroshock treatment after administration of 3-alkyl GABA. We find in this respect that the raw data tabulated in the publication substantially corresponds to that presented in the declaration before us. We find that in the original declaration of Charles P. Taylor the evidence submitted was likewise directed to the evaluation of compounds in protecting rodents, i.e., mice from seizures by being subjected to low intensity electroshock 2 hours after administration of various test compounds. See Exhibit A pages 1 and 2.

Turning to page 3 of the declaration of Charles P. Taylor, we find data submitted regarding the n-propyl analog of isobutyl GABA. We find the data reported in the declaration at levels of 3.0 mg/kg and 10 mg/kg identical with that of Table II of Exhibit D in terms of the number of mice wherein the n-propyl analog inhibited seizures. Similarly, on page 4 of the declaration the data reported for the number of mice wherein the isopropyl analog inhibited seizures is identical with that of Table II of Exhibit D. The same findings apply to the n-butyl analog on page 4 of the declaration, with respect to dosages at the 10mg/kg and 30mg/kg level. Even more significantly, the data for the racemic isobutyl derivative, declaration page 4, relied upon by the appellants to show

unusual and unexpected results are identical at all dosage levels. Indeed Taylor in his 1992 publication, Exhibit D, concludes that 3-isobutyl GABA prevents tonic extensor seizures from low intensity electroshock when given intravenously with an ED<sub>50</sub> dose of 2.1 mg/kg. See pages 105-106. Accordingly, the effects of isobutyl GABA relied upon by the appellants to show unusual or unexpected results were well known in 1992, years prior to the effective filing date of the instant application.

As we stated supra, a requirement of evidence to rebut a prima facie case of obviousness is that the difference actually obtained be unexpected by one skilled in the art at the time of the invention. The corollary to that requirement has been explicitly stated by the courts. When the results obtained by appellants, are expected beneficial results, they are evidence of obviousness, just as unexpected results are evidence of unobviousness. In re Gershon, 372 F.2d 535, 537, 152 USPQ 602, 604 (CCPA 1967). See also In re Skoner, 517 F.2d 947, 950, 186 USPQ 80, 82 (CCPA 1975)("[e]xpected beneficial results are evidence of obviousness of a claimed invention just as unexpected beneficial results are evidence of unobviousness"). Accord In re Skoll, 523 F.2d 1392, 1396-97, 187 USPQ 481, 484 (CCPA 1975).

Accordingly, unlike the situation of In re Magerlein, wherein the appellants established the unexpected superiority of the end product, on the record before us, the evidence discloses that the results obtained by the appellants for the end product is expected beneficial results known at the time of the invention. Therefore, the results do

not inure to the benefit of the intermediate of the claimed subject matter.

Based upon the above reasons, we have determined that the examiner has established a prima facie case of obviousness. Upon reconsideration of all the evidence and argument submitted by appellants, we have, determined from the totality of the record that the preponderance of the evidence weighs in favor of obviousness within the meaning of 35 U.S.C. § 103. See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

In light of the above dispositive issue, no further discussion of claim 30 is needed in affirming the decision of the examiner.

### DECISION

The rejection of claims 3 and 30 under 35 U.S.C. §103(a) as being unpatentable over Benneville is affirmed.

The decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

SHERMAN D. WINTERS  
Administrative Patent Judge

WILLIAM F. SMITH  
Administrative Patent Judge

PAUL LIEBERMAN  
Administrative Patent Judge

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Appeal No. 2003-1991  
Application No. 09/412,258

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